UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,082	12/31/2003	Timothy W. Vanderveen	IVACP 61611	2075

24201	7590	06/26/2006	

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER
WASHBURN, DOUGLAS N

ART UNIT	PAPER NUMBER
2863	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	10/750,082	VANDERVEEN ET AL.
	Examiner	Art Unit	
	Douglas N. Washburn	2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>22 July 2005</u>.
2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-17</u> is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) <u>1-17</u> is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on <u>14 March 2005</u> is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a) ☐ All   b) ☐ Some * c) ☐ None of:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)
1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date 3l DEC 2003, 22 JUL 2005
4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____ .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public
> use or on sale in this country, more than one year prior to the date of application for patent in the United
> States.

Claims 1-10 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated

by Georgi et al. (US 5,096,385) (Hereafter referred to as Georgi).

Georgi teaches:

Sampling the pressure within an infusion line (IV tubing; column 5, line 21;

figure 5, element 64) connecting a fluid container (drip chamber; column 5, line 20;

figure 5, element 62) with an infusion flow control device (infusion pump; column 3,

line 12; figure 5, element 70) at a selected frequency (predetermined sampling interval;

column 1, line 64) in regard to claim 1;

Calculating a first averaged sampled pressure value by averaging the sampled

pressure over a selected period of time (column 7, lines 56-59) in regard to claim 1;

Storing the averaged sampled pressure value in a memory (column 8, lines 9-11)

in regard to claim 1;

Calculating a second averaged sampled pressure value by averaging the

sampled pressure over a second selected period of time (column 8, lines 22-26) in

regard to claim 1;

Calculating a difference between the first averaged sampled pressure value and

the second averaged sampled pressure value (column 8, lines 11-13) in regard to

claim 1;

Providing a signal if the difference reaches a pre-determined threshold value (column 9, lines 32 and 33) in regard to claim 1;

Continuing to sample the pressure within the infusion line (IV tubing; column 5, line 21; figure 5, element 64) and calculating averaged sampled pressure values, incrementing the selected period of time for each calculation (column 7, lines 56-59) in regard to claim 2;

Comparing the latest averaged sample pressure value to a next previous averaged sampled pressure value and calculating a difference between the latest averaged sample pressure value and the next previous averaged sampled pressure value (column 2, lines 60-64) in regard to claim 2;

Providing a signal if the difference reaches a pre-determined threshold value (column 9, lines 32 and 33) in regard to claim 2;

Processing multiple averaged sample pressure values to provide an optimized measure of a rate of change of a slope of the multiple averaged sample pressure values (column 8, lines 18-22) in regard to claim 3;

Determining when the optimized measure of the rate of change indicates the existence of a pre-defined condition within the infusion line (column 8, lines 18-22) in regard to claim 3;

Providing the signal provides an indication that the container (drip chamber; column 5, line 20; figure 5, element 62) is empty (column 1, lines 26-29) in regard to claim 4;

Providing the signal provides an indication that a drip chamber (drip chamber; column 5, line 20; figure 5, element 62) associated with the container is empty (column 1, lines 26-29) in regard to claim 5;

Synchronizing (column 4, lines 25-29) the sampling with movement of a pump mechanism (infusion pump; column 3, line 12; figure 5, element 70) that causes the fluid to flow from the fluid container (drip chamber; column 5, line 20; figure 1, element 62) in regard to claim 6;

Sampling the pressure within an infusion line (IV tubing; column 5, line 21; figure 5, element 64) through direct contact with the infusion line at a location lying between a fluid movement mechanism (peristaltic fingers; column 5, lines24 and 25) in the fluid flow control device (infusion pump; column 3, line 12; figure 5, element 70) and the container (drip chamber; column 5, line 20; figure 5, element 62)in regard to claim 7;

Sampling the pressure within an infusion line (IV tubing; column 5, line 21; figure 5, element 64) connecting a primary and a secondary fluid container with a fluid flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 8;

A pressure sensor (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) in operable communication with the fluid line, the pressure sensor capable of monitoring a pressure within the fluid line (IV tubing; column 5, line 21; figure 5, element 64) and providing a signal representative of the monitored pressure in regard to claim 9;

A memory (column 8, lines 9-11) for storing pressure related values in regard to claim 9;

A processor (signal processing unit; column 5, line 43) in operable communication with the pressure sensor and the memory (figure 5), the processor programmed to receive signals from the pressure sensor (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) and sample the received signals at selected intervals (column 4, lines 25-29), the processor also programmed to calculate a first averaged sampled pressure value from the signals received during a first selected interval (column 7, lines 56-59) and store the first averaged sampled pressure value in the memory (column 8, lines 9-11), the processor also programmed to compare the stored averaged sampled pressure value with a second averaged sampled pressure value calculated during a second selected interval and provide a signal if the comparison results in a difference between the first and second calculated averaged sampled pressure values reaches a predetermined threshold (column 2, lines 60-64) in regard to claim 9;

The pressure sensor (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) is located within a housing (column 1, lines 37 and 38) of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 10;

The processor is programmed to count (column 9, lines 29-33) the number of revolutions of a fluid movement mechanism (peristaltic fingers; column 5, lines 24 and 25) of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70), and calculates the averaged pressure value when a predetermined number of revolutions have been completed (column 7, lines 56-58) in regard to claim 13;

The pressure sensor is disposed in direct contact (figure 5) with the fluid line (IV tubing; column 5, line 21; figure 5, element 64) at a location between a fluid movement mechanism (peristaltic fingers; column 5, lines24 and 25) of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) and the container in regard to claim 14;

The processor is configured to sample the received signals (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) in synchronization (column 4, lines 25-29) with movement of a fluid control mechanism forming part of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 15;

The processor is further configured to sample the pressure within the infusion line (IV tubing; column 5, line 21; figure 5, element 64) that connects a primary and a secondary fluid container with the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 16;

And the infusion flow control device comprises an infusion pump (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 17.

Claim Rejections - 35 USC § 103

2   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georgi in view of Allgeyer (US 6,847,899) (Hereafter referred to as Allgeyer).

Georgi teaches:

Sampling the pressure within an infusion line (IV tubing; column 5, line 21; figure 5, element 64) connecting a fluid container (drip chamber; column 5, line 20; figure 5, element 62) with an infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) at a selected frequency (predetermined sampling interval; column 1, line 64) in regard to claim 1;

Calculating a first averaged sampled pressure value by averaging the sampled pressure over a selected period of time (column 7, lines 56-59) in regard to claim 1;

Storing the averaged sampled pressure value in a memory (column 8, lines 9-11) in regard to claim 1;

Calculating a second averaged sampled pressure value by averaging the sampled pressure over a second selected period of time (column 8, lines 22-26) in regard to claim 1;

Calculating a difference between the first averaged sampled pressure value and the second averaged sampled pressure value (column 8, lines 11-13) in regard to claim 1;

Providing a signal if the difference reaches a pre-determined threshold value (column 9, lines 32 and 33) in regard to claim 1;

Continuing to sample the pressure within the infusion line (IV tubing; column 5, line 21; figure 5, element 64) and calculating averaged sampled pressure values, incrementing the selected period of time for each calculation (column 7, lines 56-59) in regard to claim 2;

Comparing the latest averaged sample pressure value to a next previous averaged sampled pressure value and calculating a difference between the latest averaged sample pressure value and the next previous averaged sampled pressure value (column 2, lines 60-64) in regard to claim 2;

Providing a signal if the difference reaches a pre-determined threshold value (column 9, lines 32 and 33) in regard to claim 2;

Processing multiple averaged sample pressure values to provide an optimized measure of a rate of change of a slope of the multiple averaged sample pressure values (column 8, lines 18-22) in regard to claim 3;

Determining when the optimized measure of the rate of change indicates the existence of a pre-defined condition within the infusion line (column 8, lines 18-22) in regard to claim 3;

Providing the signal provides an indication that the container (drip chamber; column 5, line 20; figure 5, element 62) is empty (column 1, lines 26-29) in regard to claim 4;

Providing the signal provides an indication that a drip chamber (drip chamber; column 5, line 20; figure 5, element 62) associated with the container is empty (column 1, lines 26-29) in regard to claim 5;

Synchronizing (column 4, lines 25-29) the sampling with movement of a pump mechanism (infusion pump; column 3, line 12; figure 5, element 70) that causes the fluid to flow from the fluid container (drip chamber; column 5, line 20; figure 1, element 62) in regard to claim 6;

Sampling the pressure within an infusion line (IV tubing; column 5, line 21; figure 5, element 64) through direct contact with the infusion line at a location lying between a fluid movement mechanism (peristaltic fingers; column 5, lines24 and 25) in the fluid flow control device (infusion pump; column 3, line 12; figure 5, element 70) and the container (drip chamber; column 5, line 20; figure 5, element 62)in regard to claim 7;

Sampling the pressure within an infusion line (IV tubing; column 5, line 21; figure 5, element 64) connecting a primary and a secondary fluid container with a fluid flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 8;

A pressure sensor (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) in operable communication with the fluid line, the pressure sensor capable of monitoring a pressure within the fluid line (IV tubing; column 5, line 21; figure 5, element 64) and providing a signal representative of the monitored pressure in regard to claim 9;

A memory (column 8, lines 9-11) for storing pressure related values in regard to claim 9;

A processor (signal processing unit; column 5, line 43) in operable communication with the pressure sensor and the memory (figure 5), the processor programmed to receive signals from the pressure sensor (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) and sample the received signals at selected intervals (column 4, lines 25-29), the processor also programmed to calculate a first averaged sampled pressure value from the signals received during a first selected interval (column 7, lines 56-59) and store the first averaged sampled pressure value in the memory (column 8, lines 9-11), the processor also programmed to compare the stored averaged sampled pressure value with a second averaged sampled pressure value calculated during a second selected interval and provide a signal if the comparison results in a difference between the first and second calculated averaged sampled pressure values reaches a predetermined threshold (column 2, lines 60-64) in regard to claim 9;

The pressure sensor (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) is located within a housing (column 1, lines 37 and 38) of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 10;

The processor is programmed to count (column 9, lines 29-33) the number of revolutions of a fluid movement mechanism (peristaltic fingers; column 5, lines 24 and 25) of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70), and calculates the averaged pressure value when a predetermined number of revolutions have been completed (column 7, lines 56-58) in regard to claim 13;

The pressure sensor is disposed in direct contact (figure 5) with the fluid line (IV tubing; column 5, line 21; figure 5, element 64) at a location between a fluid movement mechanism (peristaltic fingers; column 5, lines24 and 25) of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) and the container in regard to claim 14;

The processor is configured to sample the received signals (pressure transducer; column 5, lines 27 and 28; figure 5, element 78) in synchronization (column 4, lines 25-29) with movement of a fluid control mechanism forming part of the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 15;

The processor is further configured to sample the pressure within the infusion line (IV tubing; column 5, line 21; figure 5, element 64) that connects a primary and a secondary fluid container with the infusion flow control device (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 16;

And the infusion flow control device comprises an infusion pump (infusion pump; column 3, line 12; figure 5, element 70) in regard to claim 17.

Georgi is silent regarding:
The processor is remote from the infusion flow control device in regard to claim 11;

The processor is in communication with an information system of an institution, and wherein the signal is communicated to the information system for dissemination to at least one care giver within the institution in regard to claim 12;

Allgeyer teaches:

The processor is remote from the infusion flow control device in regard to claim 11;

The processor is in communication with an information system of an institution, and wherein the signal is communicated to the information system for dissemination to at least one care giver within the institution in regard to claim 12.

Regarding claims 11 and 12, it would have been obvious to one skilled in the art at the time of the instant invention to modify the teaching of Georgi of a processor in operable communication with a pressure sensor and a memory with the teaching of Allgeyer of control and analysis functions provided through a network to a pump, in a patient's room, a nurse's station, or elsewhere because control and analysis functions provided through a network to a pump, in a patient's room, a nurse's station, or elsewhere would have provided qualitative and quantitative information to a hospital.

Conclusion

3   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Douglas N. Washburn whose telephone number is (571) 272-2284. The examiner can normally be reached on Monday through Thursday 6:30 AM - 4:30 PM.
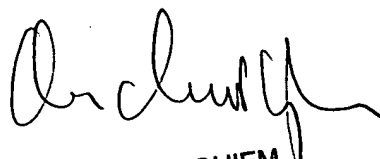
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John E. Barlow can be reached on (571) 272-2269. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR
only. For more information about the PAIR system, see http://pair-direct.uspto.gov.
Should you have questions on access to the Private PAIR system, contact the
Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like
assistance from a USPTO Customer Service Representative or access to the
automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-
1000.

DNW

MICHAEL NGHIEM
PRIMARY EXAMINER